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Subject: West Virginia officials trust shaky science in rush to restore water service: One-part-per-million safe threshold has questionable basis

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West Virginia officials trust shaky science in rush to restore water service: One-part-per-million "safe" threshold has questionable basis

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By Richard Denison

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In a press conference today outlining plans to restart the water system serving 300,000 people, West Virginia state officials and executives from the West Virginia American Water utility company stressed that levels of the toxic chemical that contaminated the supply after last week's spill had reached a "safe" level of one part per million (1 ppm), the threshold agreed upon by state and federal officials on Saturday.

Unfortunately, the science behind this standard remains unclear. Based on what we *do* know, there are good reasons to believe that officials are overlooking significant health risks.

We know, for example, that the manufacturer's Material Safety Data Sheet (MSDS) that officials say they are using as their primary source lacks any information about chronic health impacts. The major federal databases we consulted suggest such data simply do not exist for this chemical.

It also appears that officials made significant leaps in their calculation of a "safe" exposure level – including assumptions that deviate from generally accepted practices. As a result, these estimates fail to adequately account for either acute or chronic health effects from ongoing exposure to water contaminated at the 1 ppm level.

At a bare minimum, the public deserves to know a lot more about the calculations behind officials' insistence that a 1 ppm level in drinking water is safe.

Do the math

So how was this level, which is now being declared safe, derived? The short answer is, it was done through a mix of standard practice, problematic deviations from standard practice, and utter hand-waving.

I blogged earlier about how few health data are available on this chemical (4-methylcyclohexane methanol, or MCHM; its unique identifying "CAS number" is 34885-03-5). With respect to oral toxicity, there appears to be only a single study, conducted in 1990 by the chemical's producer, Eastman Chemical Company, but never made public. That study uses one of the crudest methods around for assessing how toxic a chemical is: Feed rats the chemical and determine the dose at which 50 percent of the rats die in a short period of time, typically 24 hours. This dose is called the median lethal dose, or LD50.

Using that crude test, Eastman apparently found the LD50 for this chemical was 825 milligrams per kilogram of body weight (this value is reported in Eastman's Material Safety Data Sheet (MSDS) for what it calls "crude MCHM"). Note that a "milligram per kilogram" is equivalent to a part per million, or ppm.

Officials started with that value and then applied a series of "uncertainty factors" as follows:

1. Because humans may be much more sensitive to the effects of a chemical exposure than rats, a 10-fold "interspecies extrapolation" uncertainty factor was applied. That dropped the value to 82.5 ppm.

2. Because humans differ in their sensitivity to a chemical exposure (e.g., infants or the elderly or people with an illness may suffer effects at a dose that would not affect healthy adults), another 10-fold "intraspecies extrapolation" uncertainty factor was applied. That dropped the value to 8.25 ppm.

3. Finally, acknowledging that the study in question looked only at lethality, whereas this chemical might well have other health effects short of outright killing you, a third uncertainty factor was applied. Magically, this factor was set at 8.25-fold, in order to produce the nice round number of 1 ppm as the "safe" level.

While the use of uncertainty factors is standard practice in risk assessment (being necessary because we don't generally intentionally test chemicals on people!), two major deviations from such practice were done in this case, based on highly questionable assumptions. Moreover, these calculations utterly fail to account for chronic health effects from longer-term exposure to water contaminated at the 1 ppm level. Read on for the details:

- **First, the two 10-fold uncertainty factors were erroneously applied to the LD50 value.**

Standard risk assessment practice is far different: Such factors would normally be applied to a value called the "No Observable Adverse Effect Level," or NOAEL. That is the dose at which no effect of a chemical exposure is observed. It doesn't take a risk assessor to recognize that the dose at which no effect is seen is going to typically be far, far lower than the dose that outright kills half of the exposed subjects.

In some cases, a NOAEL is not available, in which case a value called the "Lowest Observable Adverse Effect Level," or LOAEL is used instead. That is the lowest dose at which an effect is seen in a study. While that dose is clearly going to be higher than the NOAEL, it will again likely be far lower than an LD50. Even so, substituting the LOAEL for the NOAEL will often be compensated for by applying an additional uncertainty factor.

In the present case, then, officials have started with the wrong starting risk value, one that is far higher than they should have used. No doubt they did so because the values they should have used – the NOAEL or the LOAEL are not available for this chemical. But that's no excuse for not compensating for this major problem, at the very least through application of an additional large uncertainty factor.

- **Second, it was assumed without basis that any non-lethal effects of this chemical would occur at doses that were at most 8.25-fold lower than the lethal dose that would kill 50% of exposed subjects.**

This assumption can only have been pulled out of thin air. Put aside the convenience of selecting a factor that allowed a nice round number of 1 ppm to be set as the safe level. On what possible basis could it be assumed that the dose of the chemical that would, for example, be moderately toxic even in the short term to the liver or kidney, be only about one-eighth the dose that would kill someone outright in just 24 hours? Many health effects of chemicals occur at doses that are orders of magnitude lower than the lethal dose.

So let's step back and examine this 1 ppm level from another angle. The calculations would suggest that an adult who weighs 220 pounds (100 kilograms) would need to receive a dose of 100 milligrams of the chemical to suffer effects (that would be 100 milligrams per 100 kilograms of body weight, the same as 1 milligram per kilogram of body weight).

To get that dose, an individual would have to consume 100 liters of water contaminated at the 1 ppm level (that's because 1 ppm in water equals 1 milligram per liter).

While 100 liters may sound like a lot, remember that officials are saying this is the safe level for *ongoing* consumption of the water. That level of consumption could be reached by drinking just 5 liters per day for 20 days.

It also must be noted that exposure can occur not just through drinking water or using it to prepare food. Bathing or showering in such water would also add to the total exposure.

What about chronic health effects?

Last and certainly not least, none of this math adequately accounts for the concern that long-term exposure to chemicals may cause *chronic* health effects, not just the acute (short-term) toxicity – in this case, lethality – that the Eastman rat oral toxicity study considered and on which all the calculations are based.

Nor does the math account for how the chemical behaves in people – does it accumulate? Break down rapidly? Leave byproducts that are more or less toxic? Here again, the basic health data that could be used to answer such questions do not exist.

Bottom line

Now, let me be clear. I am not saying that the level of 1 ppm is unsafe. I am saying that we have no way of knowing whether or not it is safe. The data needed to make that assessment simply do not exist for this chemical.

And that distressing reality is in no small part due to the failings of our nation's chemical safety law, the Toxic Substances Control Act (TSCA) – which was the subject of my first blog post on this unfolding crisis.

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